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10/528,411	11/10/2005	Poul Boelt	55320.001001	4433

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EXAMINER
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MATTER, KRISTEN CLARETTE

ART UNIT	PAPER NUMBER
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3771

DATE MAILED: 10/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/528,411

Applicant(s)

BOELT, POUL

Examiner

Kristen C. Matter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 March 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/12/05.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Drawings***

Please see attached Notice of Draftsperson's Patent Drawing Review

### ***Specification***

The disclosure is objected to because of the following informalities: On page 2 , line 8, "need" should be replaced with --needs--.

Appropriate correction is required.

### ***Claim Objections***

Claim 8 is objected to because of the following informalities: On line 2, "fixed attached" should be replaced with --fixedly attached--.

Claim 12 is objected to because of the following informalities: On line 2, "even" should be replaced with --evenly--.

Claim 14 is objected to because of the following informalities: On lines 2-4, "the one pair of oppositely arranged air passages" and "the other pair of oppositely arranged air passages" is not totally clear. Examiner suggests replacing with --the one pair of air passages spaced 180 degrees—and --the other pair of air passages spaced 180 degrees--, respectively.

Claim 19 is objected to because of the following informalities: On line 2, "comprise" should be replaced with --comprises--.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 9, 10, 11, 15, 17, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "said attachment section" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claims 17 and 18 recite the limitation "the inner cavity" in line 2 and line 3, respectively. There is insufficient antecedent basis for this limitation in the claim. Examiner suggests replacing "the inner cavity" with --the flow passage--.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 9 recites the broad recitation

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“between 0.5-5 mm”, and the claim also recites “such as 1 or 2 mm” which is the narrower statement of the range/limitation; claim 10 recites the broad recitation “the inlet end part is 4-8 mm”, and the claim also recites “such as 6 mm” which is the narrower statement of the range/limitation; claim 11 recites the broad recitation “the outlet end part is 2-5 mm”, and the claim also recites “such as 3 mm” which is the narrower statement of the range/limitation; claim 15 recites the broad recitation “the diameter of the perforation(s) is between 1-10 mm”, and the claim also recites “such as 2-9 mm, such as 3-8 mm, such as 4-7 mm , such as 5-6 mm” which is the narrower statement of the range/limitation;

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5, 6, 7, 12, 13, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Serowski et al. (US 5937,851). Serowski et al. discloses a swivel exhaust conduit for connecting a patient mask to the delivery conduit of a positive pressure air supply. The swivel has two tubular portions, a mask connection piece 112 and a delivery conduit piece 114, which are coupled to each other and provide a clearance for exhaust to escape towards the inlet

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of the supply (see column 2, lines 30-40 and Figure 2). Mask connection piece provides a “shield” over radial holes 350 and is a tubular body of revolution as seen in Figure 2. The exhaust (venting) portion of the swivel has four spaced radial holes in a stepped portion 350 of the conduit piece 314 (see Figure 6 and column 3, lines 50-60). As can be seen in Figure 6, the radial holes 360 are spaced 90 degrees apart along the circumference of the air passage.

Regarding claim 1, the hollowed tubular member is described by delivery conduit piece 114, the perforations are described by radial holes 360, and the shielding member is described by delivery conduit piece 114.

Regarding claim 2, delivery conduit piece 114 comprises an air inlet, an air outlet, and radial holes for venting.

Regarding claim 5, the delivery conduit piece has a stepped configuration and flanges for attachment to mask connection piece 112 (see Figure 2).

Regarding claim 6, the mask connection piece is a tubular body of revolution.

Regarding claim 7, mask delivery portion is a separate piece from the delivery conduit portion that can be attached.

Regarding claims 12 and 13, Serowski et al. discloses four radial holes (perforations) spaced 90 degrees apart.

Regarding claim 21, Serowski et al. discloses supplying gas via delivery conduit end, which then either passes through the mask end to the patient or through the radial holes to atmospheric air.

Regarding claim 22, see rejection for claim 1.

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Claims 1, 2, 4, 5, 7, 8, 21, and 22 as best understood by the examiner are rejected under 35 U.S.C. 102(e) as being anticipated by Gunaratnam et al. (US 6,691,707). Gunaratnam et al. discloses a connector for a respiratory mask with a mask end for supplying respiratory gas to a patient, a supply conduit end, and a gas washout vent passage with an outlet in fluid communication with the atmosphere. Figures 2 and 3 show the connector as a cap portion 36 and a hollow body portion 34 with inlet ports 41 to a vent passage 32 for venting gas to the atmosphere.

Regarding claim 1, the hollowed tubular member is described by the body portion 34 with high pressure inlet at supply conduit end 30 and a low pressure outlet end at mask end 28. The air venting part is described by the inlet ports 41 to the vent passage 32. The shielding portion is described by the cap portion 36.

Regarding claim 2, the body portion disclosed by Gunaratnam et al. contains the inlet 30, outlet 28, and venting portion 41.

Regarding claim 4, the cap portion disclosed by Gunaratnam et al. has ridges 58 which engage with grooves 56 on the body portion to attach the two portions. When attached, vent passage 32 is formed from the “flange” part of the cap portion (seen in Figure 2) because the cap portion has a larger radial dimension than the body portion.

Regarding claim 5, the body portion disclosed by Gunaratnam et al. has grooves 56 for receiving and holding the cap portion (shield).

Regarding claim 7, the cap portion is detachable from the body portion.

Regarding claim 8, the cap portion can be fixedly attached to the body portion by the ridges 58 and grooves 56.

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Regarding claim 21, Gunaratnam et al. discloses supplying gas via supply conduit end, which then either passes through the mask end to the patient or through the venting portion to atmospheric air. The pressure drop can be controlled by changing the volume and geometry of the vent passage (see column 3, lines 50-55).

Regarding claim 22, see rejection for claim 1.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 9, 10, 11, 15, 17, 18, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunaratnam et al. The teachings of Gunaratnam et al. are discussed above.

Regarding claim 3, Gunaratnam et al. does not specifically teach that the connector is made as one piece. However, it is well known in the art that connectors in respiratory systems can be made of moldable materials such as plastic which can be made by injection molding (see Hofstetter et al. US 5,975,077). It would have been obvious to a worker of ordinary skill in the art at the time the invention was made to have made the cap portion and body portion disclosed by Gunaratnam et al. as one piece with vent passage 32 intact for quicker or cheaper manufacturing. Furthermore, applicant does not disclose that the valve being one piece solves a stated problem or has any criticality.



Regarding claims 9-11 and 15, Gunaratnam et al. does not disclose the dimensions of the venting passage, supply conduit end, mask end, or inlet ports to the vent passage. Applicant gives no criticality to the dimensions of these features nor states that the dimensions solve a stated problem or provide an advantage in the disclosure. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the dimensions of the flow passage ends within the ranges specified by the applicant for attachment to readily available face masks and tubing for respiratory gas supply. It would also have been obvious to one of ordinary skill in the art at the time the invention was made to have made the vent passage and inlet ports disclosed by Gunaratnam et al. within the ranges specified by the applicant depending on the amount of pressure reduction desired as mentioned by Gunaratnam et al. For extrinsic evidence see Lang (US 6,112,745), who discloses a slot (vent passage) of 0.3 mm for optimal pressure reduction and larger slots for better air conduction (see column 1, lines 25-40 and column 2, lines 50-60).

Regarding claims 17 and 18, Gunaratnam et al. does not disclose the amount of pressure drop to the mask end or how much of the air flowing is vented to the ambient atmosphere. Applicant gives no criticality to the pressure drop or amount of air flowing venting to atmosphere nor discloses that a drop from 6-7 bars to 2-7 cm H<sub>2</sub>O or venting at least 50% of the air flowing solves a stated problem or provides an advantage. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have produced the pressure drop claimed by the applicant or to vent at least 50% of the air flowing in the flow passage disclosed by Gunaratnam et al. depending on the respiratory system and patient (i.e., pediatric, adult, animal) the connector was being with.

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Regarding claims 19 and 20, Gunaratnam et al. does not disclose nasal prongs with two nasal air outlets. Applicant does not disclose criticality to using nasal prongs with the valve nor discloses that nasal prongs solve a stated problem or provide a particular advantage. It is well known in the art that nasal masks, facemasks, and nasal prongs can all be used to deliver CPAP treatment to a patient. Furthermore, it is well known in the art that nasal prongs have 2 air outlets (one for each nostril). For extrinsic evidence see Drew et al. (US 6,581,594) which teaches a respiratory mask with a washout vent and discloses that the term nasal mask can be used interchangeably with nasal prongs.

Claims 9, 10, 11, 15, 17, 18, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Serowski et al.

Regarding claims 9-11 and 15, Serowski et al. does not disclose the dimensions of the venting passage, supply conduit end, mask end, or inlet ports to the vent passage. Applicant gives no criticality to the dimensions of these features nor states that the dimensions solve a stated problem or provide an advantage in the disclosure. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the dimensions of the flow passage ends within the ranges specified by the applicant for attachment to readily available face masks and tubing for respiratory gas supply. It would also have been obvious to one of ordinary skill in the art at the time the invention was made to have made the vent passage and inlet ports disclosed by Serowski et al. within the ranges specified by the applicant depending on the amount of pressure reduction desired as mentioned by Serowski et al.

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Regarding claims 17 and 18, Serowski et al. does not disclose the amount of pressure drop to the mask end or how much of the air flowing is vented to the ambient atmosphere. Applicant gives no criticality to the pressure drop or amount of air flowing venting to atmosphere nor discloses that a drop from 6-7 bars to 2-7 cm H<sub>2</sub>O or venting at least 50% of the air flowing solves a stated problem or provides an advantage. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have produced the pressure drop claimed by the applicant or to vent at least 50% of the air flowing in the flow passage disclosed by Serowski et al. depending on the respiratory system and patient (i.e., pediatric, adult, animal) the connector was being with.

Regarding claims 19 and 20, Serowski et al. does not disclose nasal prongs with two nasal air outlets. Applicant does not disclose criticality to using nasal prongs with the valve nor discloses that nasal prongs solve a stated problem or provide a particular advantage. It is well known in the art that nasal masks, facemasks, and nasal prongs can all be used to deliver CPAP treatment to a patient. Furthermore, it is well known in the art that nasal prongs have 2 air outlets (one for each nostril).

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gunaratnam et al. in view of Palmer (US 5,694,922). The teachings of Gunaratnam et al. are discussed above. Gunaratnam et al. does not disclose a disposable connector. Applicant provides no criticality to the valve being disposable nor discloses that a disposable valve solves a stated problem or provides a particular advantage. Palmer teaches a swivel tube connector for a ventilating system made of an injection molded material that is disposable (see column 2, lines 50-55 and column 3,

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lines 65-70). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the connector disclosed by Gunaratnam et al. disposable for cost effective or sanitary reasons.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Gunaratnam et al. (US 2006/0137690) discloses a nasal assembly for delivering gas to a patient having an integrally formed connector portion; Jaffe et al. (US 6, 851, 425) discloses an exhaust port assembly comprising a conduit that carries a flow of gas with a vent to ambient atmosphere; Ging et al. (US 2003/019662) discloses a respiratory mask assembly with a swivel elbow defining an exhaust port and an intake port to a patient; Bordewick (US 6,431,172) discloses a nasal cannula for delivering breathable gas to a patient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Kristen C. Matter  
Examiner  
Art Unit 3771

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10/25/06